

**REMARKS**

In the present Amendment, the specification has been amended to improve its form. A marked-up copy and a clean copy of the substitute specification containing no new matter are submitted. Claim 5 has been amended to add a period at the end. The preamble of claim 9 has been amended to recite “~~The~~ A pharmaceutical composition.” Claims 11-15 and 20 have been cancelled without prejudice or disclaimer. No new matter has been added.

Upon entry of the Amendment, claims 1-9 and 24 will be pending.

In the **Interview Summary** mailed July 10, 2009, the Examiner indicated that “The attorney does not need to respond to this interview summary, this is only for clarification of those issues outlined above.”

**Information Disclosure Statement**

The Examiner has not returned a signed and initialed copy of the PTO SB/08 Form filed December 19, 2005. In the previous Office Action of November 25, 2008, the Examiner stated that the foreign patent documents (JP 5-112571, WO 02/053565, WO 97/11946) and non-patent literature document (International Search Report dated September 21, 2004) may have been misplaced and thus requested Applicants to resubmit the documents. Applicants resubmitted the documents in the response dated February 25, 2009. Further, the corresponding English publications of the three documents, listed on the PTO SB/08 Form submitted with the Information Disclosure Statement (IDS) filed March 25, 2009, have been considered by the Examiner. Accordingly, **the Examiner is respectfully requested to consider the three**

**documents and return a signed and initialed copy of the PTO SB/08 Form filed December 19, 2005.**

**Response to Objections**

The disclosure is objected to because, per the Examiner, the instant specification is not grammatically correct.

As noted, a substitute specification is being submitted to address the Examiner's concern. Withdrawal of the objection to the disclosure is respectfully requested.

Claims 11, 12 and 20 are objected to because the term "Corticotropin Releasing Factor" should not be capitalized. Claim 5 is objected to because the claim is missing a period at the end of the claim.

Claims 11, 12 and 20 have been cancelled, rendering the objection thereof moot. Claim 5 has been amended to add a period at the end. Withdrawal of the objection to claim 5 is respectfully requested.

**Response to § 112 Rejections**

Claims 11, 20 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 11 and 20 have been cancelled, rendering this rejection moot.

As to claim 24, the Examiner considers it indefinite because of the recitation of "which is superior in thermal stability."

The Examiner asserts that the term “superior in thermal stability” is a relative term and thus it is not clear what Applicant intends to claim. Also, the Examiner requests Applicant to provide guidance as to how the thermal stability is measured.

Applicants submit that the thermal stability is measured by a differential scanning calorimeter (DSC), as indicated by the disclosure at page 11, lines 13-25 of the specification. Accordingly, withdrawal of the § 112 rejection of claim 24 is respectfully requested.

Claims 11-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claims 11-15 have been cancelled, rendering this rejection moot.

**Response to § 103(a) Rejection**

Claims 1-9, 11-15, 20 and 24 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nakai et al (WO 2002/053565, U.S. equivalent 7034153 B2, “the ‘153 patent”).

Initially, Applicants point out that Nakai is not a reference under § 102(e).

Specifically, the Examiner indicates that WO 02/053565 is prior art only under 102(e) in view of its earlier U.S. effective filing date because the reference has a common assignee with the instant application. However, the PCT application of which the Nakai reference is a national stage application, was not published in English. Consequently, Nakai et al cannot be a §102(e) reference.

Turning to the merits of the rejection, Applicants submit that this rejection should be withdrawn for the reasons of record.

**Response to Double Patenting Rejection**

Claims 1-9, 11-15, 20 and 24 are rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 2 of U.S. Patent No. 7034153 ("the '153 patent").

Applicants submit that this double patenting rejection should be withdrawn for the reasons of record.

**Conclusion**

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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